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CE MARK CERTIFICATION FOR U.S. PRODUCTS

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Trade Information Center

Special thanks to Bob Straetz, Office of European Union and Regional Affairs and Sylvia Mohr, U.S. Mission to the European Union

By 2004, an estimated one half of all U.S. exports to the EU will require the CE mark (Conformite Européenne). The CE mark indicates that a company has met essential health and safety requirements for a wide range of products, including machinery, electronics, medical devices and telecommunications equipment. All companies selling products within the EU must meet CE mark requirements in order to sell their product. CE mark product certification is crucial for U.S. companies exporting to Europe. Below are questions designed to help U.S. exporters understand the CE mark

WHAT IS THE CE MARK AND WHAT IS ITS PURPOSE?

The CE mark is an indication that a company has met the essential health, safety and environmental requirements detailed in 22 European Union directives covering an array of products, including electronics, machinery, simple pressure vessels, telecommunications, medical devices, toys and others. Once a company has met these requirements, it can affix the CE mark to its products and sell them throughout the European Union without having to make separate product modifications in each EU country to which it is selling.

The purpose of the CE mark is to harmonize health, safety and environmental regulations in order to facilitate trade and ensure a baseline level of consumer safety among EU member states. If a company fails to meet CE mark requirements, its product can be held up by European customs at the point of entry and returned to the United States. If the non-CE marked product makes it through customs, CE mark enforcement officials in each member state could discover the violation while making routine checks at manufacturing centers or in stores. These enforcement agents might also discover a product in non-conformance with the CE mark after investigating an accident or in acting on a competitor's complaint. Initial CE mark violators are usually penalized by fines. Repeated violations can lead to a product being banished from the European market.

WHICH PRODUCT GROUPS DO THE CE MARKING DIRECTIVES COVER?

It is estimated that about half of all U.S. merchandise goods exports to the EU will be affected by these directives when the CE mark program is fully implemented.

The adopted CE mark (or New Approach) directives cover the following product groups: Active implantable medical devices, electrical equipment for use in explosive atmospheres, cableway installations for passengers, civil uses of explosives, construction products, electromagnetic compatibility, energy efficiency for household refrigerators and freezers, energy labeling, gas appliances, hot water boilers, in-vitro diagnostic medical devices, elevators, low voltage, machinery safety, medical devices, noise emission of outdoor equipment, personal protective equipment, pressure equipment, radio and telecommunications terminal equipment, recreational craft, satellite earth station equipment, telecommunications terminal equipment and toy safety. New Approach directives on packaging, packaging waste and marine equipment do not require the CE mark.

The one CE mark directive not yet approved by the EU is the measuring instruments directive which should be adopted sometime in 2002.

Almost all of the adopted CE mark directives are mandatory, meaning companies must meet the requirements of the directives in order to sell their products in Europe.

CAN U.S. COMPANIES SELF-CERTIFY FOR THE CE MARK?

Most products covered by the New Approach directives can be self-certified by the manufacturer. To self-certify, the manufacturer must assess the conformity of the products to the applicable directives and standards. Below is an attempt to clarify the process through five steps.

Step 1: **Identify the directives and standards that apply to your product.** A list of directives, standards and harmonized standards giving presumption of conformity is maintained on the New Approach web site, www.newapproach.org.

Step 2: **Make sure that your product is one that can be self-certified.** While most products can be self-certified, there are some that cannot. Certain high-risk products may not be self-certified. High-risk products include dangerous machines (as defined in Annex 4 of the Machine Directive), simple pressure vessels, gas appliances, and medical devices. These products require testing by an EU-affiliate lab in the U.S. that is connected to a notified body. Many U.S. testing houses act as subcontractors for the EU notified bodies. A list of notified bodies (EU-based test labs) can be located on the EU Europa web site. The list of

notified bodies and the list of test houses in the U.S. that subcontract to EU notified bodies can be obtained through the Commerce Department.

Step 3: **If your product cannot be self-certified, obtain a test result from a lab confirming that the standards were met.** It is only necessary to use an EU-affiliated lab within the United States if your company does not already abide by European standards. If the company uses European standards, it can use any lab that has the equipment to test to those standards. While the use of European harmonized standards is not required, applying EU standards is the best way to meet the requirements of the CE Mark directives.

Step 4: **Establish a technical file documenting that your product conforms to the CE Mark directive.** The main component of the technical file is the lab report showing that your product conforms to the European standard. Operating instructions are also part of the technical file.

Step 5: **Create a Declaration of Conformity.** Once the company has received the lab certificate, it is their responsibility to fill out a Declaration of Conformity indicating that the product has met CE mark requirements for any applicable directives. There is not a specific form that must be used for the Declaration of Conformity. However, a declaration must include the manufacturer's name and address, the model and serial number of the product, the CE marking directives that apply to the product, the European standards used and the signature of a company official showing that the company assumes liability for the safety of the product in the European market. The Department of Commerce's Office of European Union Affairs has sample conformity declarations available upon request.

After the Declaration of Conformity has been prepared, the manufacturer may affix the CE mark to the product. The manufacturer or its authorized representative must then be able to provide the Declaration of Conformity together with the technical file if requested by the appropriate member state authorities.

A Follow-up Step: **Stay current on new standards coming into play on your products.** A major challenge for U.S. firms is to stay current on new standards in force for their products. For example, the European standards organizations have developed some 750 standards for the low voltage directive and 175 standards for the electromagnetic compatibility directive (EMC). Not only are new standards being issued, but also these new standards, in some cases, have replaced standards that companies may have met earlier. U.S. companies that use EMC or low voltage standards that have been replaced are considered to be non-compliant with CE mark requirements. U.S. companies can keep abreast of any changes by consulting the New Approach and European Union websites listed at the end of the article.

WHAT IS THE COMMERCE DEPARTMENT DOING TO HELP U.S. COMPANIES GET THE CE MARK?

The Commerce Department has information packages for each CE mark directive available to U.S. companies. These CE mark packages contain the applicable CE mark directive, the updated list of standards, instructions on how to meet CE mark requirements, a list of labs in the U.S. (some EU-affiliate labs and some non-EU labs), a sample declaration of conformity, guides explaining the directives and other information, such as what goes into a technical file and a CE mark overview with the complete list of CE mark directives. To request an information package, contact the Commerce Department's Office of European Union Affairs, whose address and telephone number appear at the end of the article.

WHERE CAN I FIND MORE INFORMATION ON THE CE MARK?

The following web sites provide information on CE marking:

www.newapproach.org (CE mark directives and the updated list of standards).

www.europa.eu.int/comm/enterprise/newapproach/standardization (Principal EU website).

www.eurunion.org/legislat/index.htm (Delegation of the European Commission to the United States. Choose the "standards" option).

http://europa.eu.int/eurlex/en/dat/2000/c_292/c_2922000 1013en00010204.pdf (List of notified bodies, that is, the EU-based test labs).

www.conformance.co.uk/CE_MARKING/ce_content.html (UK-based consulting firm providing valuable content).

http://tradeinfo.doc.gov (Select Europe for general information on exporting to Western Europe).

In addition, the following contacts within the Department of Commerce are valuable sources of information:

- Trade Information Center,Phil Combs or JoAnn Queen; Tel: (800) USA-TRAD(E), Email: TIC@ita.doc.gov
- Office of the European Union and Regional Affairs, Bob Straetz, CE mark specialist; Tel: (202) 482-4496; Fax: (202) 482-2897.
- U.S. Mission to the European Union, Suzanne Sene & Sylvia Mohr; Tel: (32 2) 513-2674 or 2675; Fax: (32 2) 513-1228.

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